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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shmuel Ben Muvhar

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EXAMINER

LANG, AMY T

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,966	Applicant(s) BEN MUVHAR, SHMUEL	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/04/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-17 and 19-22 are pending, claim 18 is cancelled, and claims 21 and 22 are new.

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/534,968, PCT/IL01/00284, PCT/IL02/00805, PCT/IL03/00303, IL 151162, IL 152366, and IL 153753, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, these applications do not disclose a balloon member comprising staves or a flexible band comprising a flow passage which through blood flows at a restricted rate as disclosed in the instant Figure 5.

Oath/Declaration

2. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application or US application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date. Specifically, the oath or declaration does not acknowledge US 09/534,968, PCT/IL01/00284, PCT/IL/02/00805, PCT/IL03/00303, IL 151162, IL 152366, IL 153753.

Claim Objections

3. **Claim 17** is objected to because of the following informalities: Claim 17 recites “a flow channel having *an* cross-section” which should be replaced with “having *a* cross-section.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 1-11** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(i) claim 1 recites an intra-vascular balloon comprising a balloon body and at least one stave attached to said balloon. However, it is the examiner's position that the instant specification does not support this limitation. The only reference to "staves" in the instant specification is directed to Figure 5 (see page 17, lines 24-31). However, the staves (532, 534, 536, 538) are attached to a member made of shape memory material in Figure 5, not a balloon (see page 18, lines 1-4). Although Figure 10 discloses a balloon catheter comprising a balloon, no staves are disclosed in this Figure. Instead, the instant specification teaches the balloon attached to "expansion rods" (see page 20, lines 16-20). Therefore, it is the examiner's position that the instant specification does not support a balloon attached to staves.

(ii) claim 1 recites wherein the stave and balloon are made from different materials. However, it is the examiner's position that the instant specification does not support this limitation since the specification does not positively recite two different materials. Although the specification does teach that "the balloon and/or one or more staves comprise materials configured to reduce in size to a compact profile," this teaching does not necessarily infer two different materials. For instance, the balloon could comprise a certain material of a certain thickness that allows it to reduce in size to a compact profile. The staves could also comprise this same material but a thicker thickness so that it is not configured to reduce in size to compact profile. Therefore, although the balloon and staves comprise the same material, only the balloon is

configured to reduce in size to a compact profile. Therefore, it is the examiner's position that the instant specification does not support this limitation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-17** are rejected under 35 U.S.C. 102(b) as being anticipated by Klein (US 5,863,284).

With regard to **claims 1, 4, 9, and 10**, Klein discloses a balloon catheter comprising a balloon body (32) attached to staves (18) (Figures 1A, 3, and 4; column 13, line 66 through column 14, lines 9). The balloon comprises an elastomeric material, specifically polyurethane, while the staves (18) comprise a radioactive material so that the two members are made of different materials (column 10, lines 15-28; column 13, lines 11-30). Klein further teaches wherein the balloon expands the staves to apply contact force to a vessel lumen (column 10, lines 1-7).

With regard to **claims 2 and 11**, as shown in Figures 2 and 3, the balloon is elongate and the staves are provided along a dimension of the balloon.

With regard to **claim 3**, shaft (33) clearly overlaps the instantly claimed tether (Figure 2).

With regard to **claim 5**, as shown in Figure 4, the staves are attached to each other at their proximal and distal ends.

With regard to **claims 6 and 7**, in one embodiment the staves are directly attached to the balloon so that the staves modify the geometry of the balloon when not inflated (column 9, lines 55-60). Furthermore, the staves are then configured to compact said balloon in a resting condition.

With regard to **claim 8**, since the staves apply radially outward pressure when inflated, it is the examiner's position that the staves are configured to also apply radially outward pressure when in a resting condition (column 14, lines 5-9).

8. **Claims 12-16 and 22** are rejected under 35 U.S.C. 102(b) as being anticipated by Kavteladze (US 5,863,411).

With regard to **claim 12**, Kavteladze discloses a vascular implant comprising a flexible band (16) having a diameter suitable for implantation in a blood vessel (column 5, lines 43-50) and a plurality of elongate axial elements (12) mounted on said band. As shown in Figure 3, the flexible band (16) comprises an inner opening which clearly overlaps the instantly claimed flow passage. When implanted within a blood vessel, this flow path would inherently restrict the flow of blood due to the small opening and members 12 impeding blood flow.

With regard to **claim 13**, the flexible band (16) is disclosed as thin (Figure 4).

With regard to **claim 14**, the flexible band has a thickness suitable for restricting blood flow (Figure 3).

With regard to **claim 14**, as shown in Figure 3, the flexible band (16) has a length substantially smaller than the length of the elements (12).

With regard to **claim 16**, the flexible band is elastic (column 5, lines 30-33, 46).

9. **Claims 17 and 20** are rejected under 35 U.S.C. 102(b) as being anticipated by Ruiz (US 6,120,534).

With regard to **claim 17**, Ruiz discloses a blood flow reducing implant comprising a body (10) defining a flow channel (20) having a cross section which is progressively restricted along an axial direction (Figure 2A, 13), in which the smallest diameter of a cross-section is sized for passage of a guidewire (30; Figure 4B) and blockage of substantially all blood-flow there through (column 4, lines 60-67).

With regard to **claim 20**, said smallest diameter (13) is restricted by an elastic sheath (Figure 2A, 16).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. **Claims 21, 12, and 22** are rejected under 35 U.S.C. 102(e) as being anticipated by Morris (US 2004/0158280 A1).

As shown in Figure 1 and 6B, Morris discloses a vascular implant comprising a flexible band (32) having a flow passage ([0069]). When the implant is placed within a vessel, the perforations in the band material would restrict blood flowing through the

flow passage (Figure 1). Klein teaches wherein a plurality of elongate elements (21, 23, 25, 27) are mounted on the outside of the band ([0081]; Figure 6B).

Claim Rejections – 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claim 19** rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz (US 6,120,534).

Ruiz does not specifically disclose wherein the flow channel blocks over 95% of blood flow. However, Ruiz teaches that the cross-section of the flow channel can be varied (column 3, lines 42-48). Therefore, a cross-section to block 95% of blood flow would have been obvious to one of ordinary skill at the time of the invention since it would involve a mere change in size of the device. A change in size is generally

recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Response to Arguments

14. Applicant's arguments, filed 11/19/2007, with respect to the Drawings have been fully considered and are persuasive. The objection has been withdrawn.

15. Applicant's arguments filed 11/19/2007 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that the implant of Kavteladze does not restrict the flow of blood since it functions as a vessel occlusion device that stops blood flow completely.

With respect to argument (A), it is the examiner's position that Kavteladze merely states wherein the implant "may completely obturate a vessel lumen" (column 5, lines 443-46). Therefore, Kavteladze does not disclose wherein the implant is intended to always completely stop blood flow, instead Kavteladze teaches in one embodiment where blood flow is completely stopped. Therefore, Kavteladze also teaches embodiments where blood flow is not completely stopped.

Specifically, applicant argues (B) that Ruiz does not disclose an implant blocking substantially all blood flow since it is placed within the pulmonary arteries.

With respect to argument (B), the implant of Ruiz can be utilized in other vessels than the pulmonary arteries (column 3, lines 28-33). Furthermore, since the constriction of the implant can be varied, it is the examiner's position that the implant is capable of blocking over 95% of blood flow in a vessel.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

03/18/2008

/Amy T Lang/

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731